UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,918	06/13/2001	Gordon W. Glazner	84894-602	2276

23529 7590 06/25/2004

ADE & COMPANY
1700-360 MAIN STREET
WINNIPEG, MB R3C3Z3
CANADA

EXAMINER	
TRAVERS, RUSSELL S	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/878,918	GLAZNER, GORDON W.	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *6 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The election and amendment filed January 14, 2004 have been received and entered into the file.

Claims 6 and 32-34 are presented for examination.

Applicant's election without traverse of group II, claims 6 and 32-34 in Paper filed January 14, 2004 is acknowledged.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria defining those compounds possessing either "protease inhibitor" activity, or "reverse transcriptase inhibitor" activity envisioned as useful for practicing the instant claims. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number those compounds envisioned as useful for practicing the instant claims possessing either "protease inhibitor" activity, or "reverse transcriptase inhibitor" activity examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all those compounds possessing either "protease inhibitor" activity, or "reverse transcriptase inhibitor" activity envisioned as useful for practicing the instant claims, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to

provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim 34 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6 and 32-33 are rejected under 35 U.S.C. § 102(a) as being anticipated by Mayne et al, of record.

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by

the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 6 and 32-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Pettit et al and Stingl et al, in view of DeBarieri et al.

Pettit et al and Stingl et al teach the claimed xestospongin D and xestospongin E respectively as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These compounds were administered at dosages between 0.0006 micrograms per milliliter and 25 micrograms per milliliter, encompassing those dosage ranges herein recited. These medicaments are taught as broadly useful for treating retroviral infections (murine P388 lymphocytic leukemia and L1210) respectively DeBarbieri et al teach P388 cancer cells and I1210 cancer cells as having a retroviral etiology, and agents treating these retro-viral etiological agents treat these neoplastic conditions (see column 5, line 59 to column 6, line 13, and figures 13-15). The use of various xestospongin compounds to treat retroviral infections broadly in P388 cells and I1210 cells would have been viewed by the skilled artisan as treating retroviral infections generally. Claims 6 and 32-33, and the primary references, differ as to:

1) employment of these medicaments to treat HIV infections and

2) administration of the specific medicaments.

Possessing these teachings of effective anti-retroviral therapy for two distinct retroviral etiological agents employing various xestospongin compounds would have motivated the skilled artisan to administer the instant xestospongin compounds, which are taught as possessing broad anti-retroviral activity, to treat all retroviral diseases; absent information to the contrary. This broad antiretroviral activity possessed by the prior art xestospongin compounds would have motivated the skilled artisan to employ

these compounds, and related compounds to treat retro-viral infections broadly, and enjoy a reasonable expectation of effectively treating HIV.

The skilled artisan, possessing a compound for an old and well known therapeutic use possesses that compounds isomers, analogs, homologs, bioisosteres for the same use. Attention is directed to *In re Ward* 141 USPQ 227 (CCPA 1964) and *Galaxo Operations U.K. Ltd. V. Quigg* 13 USPQ2d 1628, setting forth guidelines regarding therapeutic compounds relationships. Those compounds taught as obvious over the therapeutic compound are isomers, analogs, homologs and bioisosteres. In the instant case, Applicants attempt to capture these obvious variants of the old and well known antiretroviral xestospongin therapeutic compounds. Absent an illustration of unexpected benefits residing in the specific compounds herein claimed, the instant claims remain properly rejected under 35 USC 103.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Absent information to the contrary, the skilled artisan would have seen the selection of one or another conventional administration route as the simple selection between obvious alternatives. Possessing the examiner cited teachings, the skilled artisan would have been motivated to employ the claimed active ingredients to treat neurological alchemic conditions, in the manner recited in the instant claims, absent information to the contrary.

Claim 34 is rejected under 35 U.S.C. § 103 as being unpatentable over Pettit et al and Stingl et al, in view of DeBarieri et al, as set forth above for claims 6 and 32-33, in further view of Rideout et al. .

Pettit et al and Stingl et al teach the claimed xestospongin D and xestospongin E respectively as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These compounds were administered at dosages between 0.0006 micrograms per milliliter and 25 micrograms per milliliter, encompassing those dosage ranges herein recited. These medicaments are taught as useful for treating retroviral infections (murine P388 lymphocytic leukemia and L1210 leukemia) respectively, viewed by the skilled artisan as treating retroviral infections generally. Claim 34, and the primary references, differ as to:

1) concomitant employment of these medicaments to treat HIV infections.

Attention is directed to Rideout et al teaching AZT as old and well known for treating HIV infections. It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-viral agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Travers, J.D, Ph.D.
Primary Examiner
Art Unit 1617